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Monitoring Device Acceptance in Implantable Cardioverter Defibrillator Patients Using the Florida Patient Acceptance Survey

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Background: *Patient device acceptance might be essential in identifying patients at risk for adverse patient-reported outcomes following implantation of an implantable cardioverter defibrillator (ICD). We examined the validity and reliability of the Florida Patient Acceptance Scale (FPAS) and identified correlates of device acceptance in a Dutch cohort of ICD patients.*

Methods: *Patients with a first-time ICD (N = 272, mean age = 59.2 ± 11.9, 82% men) recruited from the Erasmus Medical Center, Rotterdam, or the Medisch Spectrum Twente, Enschede, The Netherlands completed the FPAS, the Type D Scale, and the Hospital Anxiety and Depression Scale.*

Results: *Exploratory and confirmatory factor analyses indicated that eliminating three items from the FPAS, leaving 12 items contributing to three factors, is equivalent to the original four-factor version of the FPAS. The abbreviated FPAS had a high internal consistency both for the total scale and all subscales, with Cronbach's alphas ranging from 0.76 to 0.82. Anxiety (odds ratio [OR]: 9.75; 95% confidence interval [CI]: 2.38–39.87; P = 0.002), depression (OR: 2.96; 95% CI: 0.98–8.93; P = 0.05), and the distressed (Type D) personality (OR: 5.04; 95% CI: 1.50–16.92; P = 0.01), but not demographic and clinical factors including shocks, were significant independent correlates of poor device acceptance.*

Conclusion: *A shortened 12-item, three-factor version of the FPAS was shown to be a valid and internally consistent instrument to assess device acceptance in Dutch ICD patients. Psychological but not clinical factors were the primary correlates of device acceptance, which underlines the importance of taking into account the patient's psychological profile when seeking to identify patients at risk for adjustment difficulties after ICD implantation. (PACE 2011;XX:1–10)*

Florida patient acceptance survey*, *implantable cardioverter defibrillator*, *anxiety*, *depression*, *Type D personality

Introduction

Implantable cardioverter defibrillator (ICD) therapy is the treatment of choice for preventing sudden cardiac death in patients who have survived life-threatening arrhythmias (secondary prevention) or are at high risk for these arrhythmias (primary prevention).[1] Although the ICD is generally well tolerated and perceived as a potential lifesaver by the majority of patients,[2,3] a subset of patients suffer from emotional distress and poor quality of life after ICD implantation.[4,5]

Patient device acceptance is one of the factors that might be essential in identifying patients at risk for these adverse patient-reported outcomes, as poor acceptance has been associated with psychological distress and an impaired quality of life in ICD patients.[2,6] Device acceptance refers to the psychological accommodation and understanding of the device and the derivation of benefit in terms of biopsychosocial functioning.[7] Previous studies

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suggest that device acceptance is not determined by ICD indication, ICD shocks, time since implantation, or device or lead advisory notices,[8–10] but rather by the presence of symptomatic heart failure and psychological factors, such as anxiety, depressive symptoms, and a distressed (Type D) personality.[2,6,11] The latter studies used the Florida Patient Acceptance Survey (FPAS), which is one of the few standardized and validated instruments available to measure ICD acceptance.[7]

The psychometric properties of the FPAS have previously been investigated in North American and Danish ICD patients samples.[7,11] Results showed that the FPAS has good validity and internal consistency. The objectives of the current study were to (1) examine the psychometric properties (i.e., factor structure, internal consistency, and divergent validity) of the FPAS, and (2) identify correlates of device acceptance, in two independent cohorts of Dutch ICD patients assessed at 10 days and 12 months postimplantation, respectively.

Methods

Study Design and Participants

The sample consisted of patients who had their first ICD implanted between August 2006 and January 2009 at the Erasmus Medical Center, Rotterdam, or the Medisch Spectrum Twente, Enschede, the Netherlands. Patients included in Rotterdam participated in the ongoing Mood and personality as precipitants of arrhythmia in patients with an Implantable cardioverter Defibrillator: A prospective Study (MIDAS). Patients included in Enschede participated in the Twente ICD Cohort Study (TICS). For both hospitals, exclusion criteria were age <18 years, significant cognitive impairments, a history of psychiatric illness other than affective/anxiety disorders, a life expectancy less than 1 year, and insufficient knowledge of the Dutch language. At 10 days (Rotterdam) or 12 months (Enschede) postimplantation, patients were asked to complete a set of standardized and validated questionnaires. The study protocol was approved by the Medical Ethics Committees of the participating hospitals. The study was conducted in accordance with the Helsinki Declaration, and all patients provided written informed consent.

Measures

Demographic and Clinical Variables

Information on sex, age, etiology, ICD indication, New York Heart Association (NYHA) functional class, left ventricular ejection fraction (LVEF), diabetes mellitus, and cardiac medication use were retrieved from patients' medical records at time of implantation. Information on ICD shocks was obtained via device interrogation, while information on smoking was obtained by means of a purpose-designed question in the questionnaire.

Device Acceptance

The FPAS asks patients to rate the extent to which they agree with 18 statements that describe living with a medical device.[7] Items are rated on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree), with a high score indicating better device acceptance. Of all items, 15 contribute to four subscales: (1) Return to function (four items); (2) Device-related distress (five items); (3) Positive appraisal (four items); (4) Body image concerns (two items). The remaining three items are filler items; these are independent from the factored subscales and total scores and do not reflect device acceptance.[7] Hence, they are not included in the current analyses. A total score based on the 15 items may also be calculated. Total and subscale scores are linearly converted into a score between 0 and 100. A high score on Return to function and Positive appraisal means better acceptance, while a high score on Device-related distress and Body image concerns represents less acceptance. The convergent and divergent validity of the FPAS are good, and the scale has been shown to be internally consistent, as indicated by Cronbach's alphas ranging from 0.74 to 0.83.[6,11] For the current study, the FPAS was translated from English into Dutch and back-translated according to standard procedures.

Type D Personality

The distressed (Type D) personality was assessed with the 14-item Type D scale (DS14).[12] Type D personality is defined by a general propensity to experience increased negative emotions paired with the nonexpression of these emotions in social interaction, due to fear of rejection or disapproval by others. The DS14 consists of two subscales, Negative affectivity and Social inhibition, each comprising seven items. Items of the DS14 are answered on a 5-point Likert scale ranging from 0 (false) to 4 (true), with total scores for each subscale ranging from 0 to 28. Only patients scoring high on both subscales according to a standardized cut-off score $\geq$10 are classified as having a Type D personality.[12,13] The DS14 is a valid and reliable scale with Cronbach's alphas of 0.88 and 0.86 and a high test-retest reliability over a 3-month period of $r = 0.72$ and 0.82 for the Negative affectivity and Social inhibition subscales, respectively.[12] Type D personality has previously been associated with increased distress, poor quality of life, and

morbidity and mortality in ICD patients.[14–17] The DS14 was included to examine the divergent validity of FPAS and the role of personality as a correlate of patient device acceptance.

Anxiety and Depressive Symptoms

Anxiety and depressive symptoms were measured with the Hospital Anxiety and Depression Scale (HADS), a 14-item self-report questionnaire.[18] The anxiety and depression subscales both consist of seven items answered on a 4-point Likert scale ranging from 0 to 3, with a score range of 0–21. On both subscales, a cut-off $\geq$8 was used to indicate probable levels of clinical anxiety and depression, respectively. A review of 15 international studies using the HADS supports the use of this cut-off, as it yields an optimal balance between sensitivity and specificity.[19] The Dutch version of the HADS has been shown to be a valid and reliable instrument, with Cronbach's alphas ranging from 0.81 to 0.84 and from 0.71 to 0.86, and test-retest reliability over a mean 3-week period being r = 0.89 and 0.86 for the anxiety and depression subscales, respectively.[20] The HADS was used to evaluate the divergent validity of the FPAS and the association between anxiety and depressive symptoms and device acceptance.

Statistical Analyses

Patient demographic and clinical baseline characteristics, stratified by center, were compared with the χ^2 test for discrete variables and the Student's *t*-test for continuous variables. Principal component analysis (PCA) with varimax rotation was used to determine the factor structure of the FPAS. Prior to the PCA, Bartlett's test of sphericity and the Kaiser-Meyer-Olkin measure of sampling adequacy (KMO-index) were examined to evaluate whether the data fulfilled the assumptions for carrying out a PCA. Eigenvalues and scree plot were used to determine the number of factors to extract. To validate the factor structure of the FPAS, we also performed confirmatory factor analysis using maximum likelihood estimation. Three overall goodness-of-fit indices (i.e., χ^2, root mean square error of approximation [RMSEA], and comparative fit index [CFI]) were calculated. A nonsignificant χ^2 indicates a perfect fit, while a reasonably good fit between the model and the observed data is obtained when RMSEA is $\leq$0.06 and CFI is $\geq$0.95.[21] Cronbach's alpha and the mean interitem correlation (MIIC) were calculated to examine the internal consistency of the FPAS subscales. MIIC was used in addition to Cronbach's alpha, since Cronbach's alpha is highly dependent on the number of items in each scale and hence prone to be inflated when the number of items is high. MIIC should fall in an optimal range between 0.20 and 0.50,[22] but should be no less than 0.15.[23]

Prior to multivariable logistic regression analysis to determine correlates of poor device acceptance, the FPAS total score was dichotomized, using the lowest tertile to indicate poor device acceptance compared with the other two tertiles representing good device acceptance. Dichotomization has been advocated earlier to enhance clinical interpretability.[24] Results of the logistic regression analysis are presented as odds ratios (ORs) with 95% confidence intervals (CIs). All tests were two-tailed. A P-value of $<$0.05 was used to indicate statistical significance. The analyses were performed using SPSS 17.0 and AMOS 19.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

Patient Characteristics

Table I displays demographic and clinical characteristics at baseline, and psychological characteristics at follow-up, stratified by center. Patients included in Enschede were on average older (61.9 vs 56.5 years, P $<$ 0.001), more likely to use diuretics (66.2% vs 48.5%, P = 0.003), and less likely to have an LVEF of $<$35% (68.2% vs 74.3%, P = 0.01) at time of implantation compared with patients included in Rotterdam. There were no other significant differences in demographic, clinical, or psychological characteristics between the two cohorts. In total, 25 patients (9.2%) had received (in)appropriate ICD shock(s) during follow-up; 23 of them belonged to the Enschede cohort which was assessed at 12 months postimplantation. Only two patients in the Rotterdam cohort had experienced an ICD shock during the short follow-up period of 10 days.

Of note, there were no significant differences in baseline characteristics of patients with poor versus good device acceptance (results not shown). However, patients with poor device acceptance were more likely to have a Type D personality (35.8% vs 14.2%, P $<$ 0.001) and to report high levels of anxiety (35.8% vs 5.5%, P $<$ 0.001) and depression (40.7% vs 9.3%, P $<$ 0.001) postimplantation, compared to patients with good device acceptance.

Factor Structure of the FPAS

Factor analysis was performed to examine the structural validity of the FPAS. The KMO-index (0.81) and Bartlett's test of sphericity (P $<$ 0.001) indicated that the data fulfilled the assumptions for carrying out a factor analysis. The eigenvalues $>$1 criterium confirmed the four-factor structure of the FPAS (Table IIA). The four factors accounted

Table I.

Baseline Characteristics for the Total Sample and Stratified by Center

	Total (N = 272)	Rotterdam (n = 136)	Enschede (n = 136)	P
Demographic factors				
Age, mean (SD)	59.2 (11.9)	56.5 (11.8)	61.9 (11.4)	< 0.001***
Women	47 (17.3)	27 (19.9)	20 (14.7)	0.26
Smoking	44 (16.2)	17 (12.5)	27 (19.9)	0.12
Clinical factors				
Secondary prevention	76 (27.9)	34 (25.0)	42 (30.9)	0.28
NYHA class III/IV	73 (26.8)	43 (31.6)	30 (22.1)	0.08
LVEF <35%	193 (71.0)	101 (74.3)	92 (68.2)	0.01*
Ischemic etiology	167 (61.4)	80 (58.5)	87 (64.0)	0.38
Diabetes	41 (15.1)	17 (12.5)	24 (17.6)	0.24
Medication				
Amiodarone	24 (8.8)	10 (7.4)	14 (10.3)	0.39
β-blockers	220 (80.9)	105 (77.2)	115 (84.6)	0.12
Digoxin	38 (14.0)	23 (16.9)	15 (11.0)	0.16
Statins	174 (64.0)	80 (58.8)	94 (69.1)	0.08
ACE inhibitors	189 (69.5)	92 (67.6)	97 (71.3)	0.51
Diuretics	156 (57.4)	66 (48.5)	90 (66.2)	0.003**
Psychological factors		10 days	12 months	
FPAS total score, mean (SD)	74.4 (14.2)	72.9 (13.7)	75.9 (14.5)	0.08
Type D personality	55 (20.2)	28 (20.6)	27 (19.9)	0.76
High anxiety†	40 (14.7)	22 (16.2)	18 (13.2)	0.48
High depression†	50 (18.4)	24 (17.6)	26 (19.1)	0.78

Results presented as% (n) unless otherwise indicated.
†≥8 points on the HADS subscale.
ACE = angiotensin-converting enzyme; NYHA = New York Heart Association functional class; LVEF = left ventricular ejection fraction; SD = standard deviation.
*P ≤ 0.05; **P ≤ 0.01; ***P ≤ 0.001.

for 64.4% of the variance (factor 1 [Device-related distress] = 30.5%; factor 2 [Positive appraisal] = 13.8%; factor 3 [Return to function] = 12.7%; factor 4 [Body image concerns] = 7.4%). However, the scree plot indicated a marked "elbow" that inflected after the third factor. Also, the factor loading for item 12 on its supposed factor (i.e., Device-related distress) was low (0.03), with this item loading higher on factor 4 (i.e., Body image concerns; factor loading = 0.68). Factor 4 had an eigenvalue of 1.12 and explained only 7.4% of the variance in device acceptance.

Hence, we reran the factor analysis with 12 items, excluding the three items loading on factor 4, that is, item 12 ("I am careful when hugging and kissing my loved ones"), 14 ("I feel that others see me as disfigured by my device"), and 15 ("I feel less attractive because of my device"). This yielded a three-factor structure (Table IIB), with the three factors accounting for 63.6% of the variance (factor 1 = 34.9%; factor 2 = 16.9%; and factor 3 = 11.8%) and all items loading on their expected factors. To verify our results, we performed confirmatory factor analyses with 15 items (four factors) and 12 items (three factors), respectively. The χ^2 test was statistically significant for both models ($\chi^2(84) = 199.0$; $P < 0.001$, and $\chi^2(51) = 99.5$; $P < 0.001$, respectively), indicating that both models do not fit the data perfectly. However, the χ^2 difference test was significant ($\chi^2_{diff}(33) = 99.44$; $P < 0.05$), which suggests that the three-factor model provides a significantly better fit to the data than the four-factor model. Also, the two other goodness-of-fit indices slightly favored the three-factor model over the four-factor model (RMSEA = 0.06; P = 0.18 vs RMSEA = 0.07; P = 0.004, and CFI = 0.96 vs CFI = 0.92, respectively).

Internal Consistency

The internal consistency of the four subscales (Device-related distress = 0.75; Positive appraisal = 0.76; Return to function = 0.80; and Body image concerns = 0.82) and the total scale (0.82), as measured by Cronbach's alpha, was acceptable (Table IIA). MIICs for three of the four subscales (Device-related distress = 0.40; Positive

Table II.

Structural Validity and Internal Consistency of the Dutch FPAS

(A) 15 Items, Four Factors

FPAS Items	I	II	III	IV	Internal Consistency
Device-related distress					
(1) Thinking about the device makes me depressed.	**0.82**	−0.19	0.16	0.01	0.59
(2) When I think about the device, I avoid doing things I enjoy.	**0.80**	−0.09	0.29	0.10	0.66
(3) I avoid my usual activities because I feel disfigured by the device.	**0.70**	−0.11	0.06	0.32	0.59
(4) It is hard for me to function without thinking about my device.	**0.74**	−0.10	0.16	0.21	0.62
(12) I am careful when hugging and kissing my loved ones.	**0.03**	−0.10	0.11	0.68	0.23
Eigenvalue = 4.58				$\alpha = 0.75$, MIIC = 0.40	
Positive appraisal					
(5) My device was my best treatment option.	−0.09	**0.66**	−0.08	−0.07	0.44
(7) I am safer from harm because of my device.	−0.08	**0.84**	−0.12	−0.04	0.56
(8) The positive benefits of this device outweigh the negatives.	−0.09	**0.81**	−0.05	−0.01	0.58
(10) I would receive this device again.	−0.16	**0.77**	−0.06	−0.14	0.66
Eigenvalue = 2.06				$\alpha = 0.76$, MIIC = 0.44	
Return to function					
(6) I am confident about my ability to return to work if I want to.	−0.01	0.22	−**0.66**	0.17	0.48
(13) I have returned to a full life.	−0.20	0.24	−**0.70**	−0.07	0.70
(17) I am not able to do things for my family the way I used to.	0.15	0.10	**0.80**	0.11	0.64
(18) I am concerned about resuming my daily physical activities.	0.31	−0.02	**0.78**	0.14	0.64
Eigenvalue = 1.91				$\alpha = 0.80$, MIIC = 0.50	
Body image concerns					
(14) I feel that others see me as disfigured by my device.	0.19	−0.03	−0.01	**0.85**	0.69
(15) I feel less attractive because of my device.	0.28	−0.10	−0.02	**0.79**	0.69
Eigenvalue = 1.12				$\alpha = 0.82$, MIIC = 0.69	

(B) 12 Items, Three Factors

FPAS Items	I	II	III	Internal Consistency
Device-related distress				
(1) Thinking about the device makes me depressed.	**0.77**	−0.19	0.17	0.68
(2) When I think about the device, I avoid doing things I enjoy.	**0.81**	−0.09	0.28	0.72
(3) I avoid my usual activities because I feel disfigured by the device.	**0.77**	−0.12	0.04	0.59
(4) It is hard for me to function without thinking about my device.	**0.77**	−0.10	0.15	0.63
Eigenvalue = 4.19	$\alpha = 0.82$, MIIC = 0.54			

Continued

Table II.

Continued

(B) 12 Items, Three Factors FPAS Items	I	II	III	Internal Consistency
Positive appraisal				
(5) My device was my best treatment option.	−0.09	**0.67**	−0.09	0.44
(7) I am safer from harm because of my device.	−0.08	**0.84**	−0.12	0.56
(8) The positive benefits of this device outweigh the negatives.	−0.08	**0.81**	−0.06	0.58
(10) I would receive this device again.	−0.22	**0.77**	−0.03	0.66
Eigenvalue = 2.03	$\alpha = 0.76$, MIIC = 0.44			
Return to function				
(6) I am confident about my ability to return to work if I want to.	0.06	0.22	**−0.70**	0.48
(13) I have returned to a full life.	−0.23	0.23	**−0.69**	0.70
(17) I am not able to do things for my family the way I used to.	0.20	0.10	**0.78**	0.64
(18) I am concerned about resuming my daily physical activities.	0.36	−0.01	**0.76**	0.64
Eigenvalue = 1.42	$\alpha = 0.80$, MIIC = 0.50			
Items not included in this analysis				
(12) I am careful when hugging and kissing my loved ones.				
(14) I feel that others see me as disfigured by my device.				
(15) I feel less attractive because of my device.				

Items assigned to a factor are presented in bold.

appraisal = 0.44; and Return to function = 0.50) and the total scale (0.25) were also within the optimal range of 0.20–0.50, except for the MIIC for Body image concerns (0.69). After excluding items 12, 14, and 15 (Table IIB), the internal consistency of the Device-related distress subscale increased (0.82), but the MIIC for this subscale fell just outside the optimal range (0.54). For the total scale, the internal consistency remained stable (0.82) and the MIIC stayed within the optimal range (0.28).

Of note, analyses for the two cohorts separately did not yield significantly different results concerning the factor structure and internal consistency of the FPAS. However, as the results concerning the divergent validity and correlates of the FPAS did differ between the two cohorts, these results will be presented separately in the subsequent sections.

In both cohorts, the FPAS, DS14, and HADS were completed at the same point in time (i.e., for the Rotterdam cohort all at 10 days and for the Enschede cohort all at 12 months postimplantation), so the results are cross-sectional. Also, since the 12-item version of the FPAS seemed to be a better measure psychometrically, this version will be used from here on for all analyses. Mean scores and corresponding standard deviations at item level and for the subscales, and the scoring algorithm for the 12-item version, are displayed in the Appendix.

Divergent Validity

The correlation matrix on scale scores between FPAS, DS14, and HADS is shown in Table III, stratified by center.

In the Rotterdam cohort (10 days postimplantation), the FPAS Positive appraisal subscale did not significantly correlate with the Negative affectivity subscale of the DS14. For the other subscales and total score, the overlap between the FPAS and Negative affectivity in terms of shared variance ranged from 14% to 19%. The FPAS Return to function subscale did not significantly overlap with the DS14 Social inhibition subscale; for the other (sub)scales the shared variance ranged from 3% to 7%. The overlap between the FPAS and HADS anxiety ranged from 19% to 28%, but anxiety was not significantly correlated with FPAS Positive appraisal. The shared variance

Table III.

Correlation Matrix on (Sub)Scale Scores (FPAS, DS14, HADS), Stratified by Center

	1	2	3	4	5	6	7	8
(1) FPAS: Return to function	–	0.42***	0.22**	0.79***	−0.38***	−0.17	−0.44***	−0.57***
(2) FPAS: Device-related distress	0.44***	–	0.33***	0.79***	−0.43***	−0.23**	−0.58***	−0.50***
(3) FPAS: Positive appraisal	0.25**	0.31***	–	0.63***	−0.13	−0.18*	−0.12	−0.20*
(4) FPAS: Total (12 items)	0.79***	0.74***	0.71***	–	−0.44***	−0.26**	−0.53***	−0.59***
(5) DS14: Negative affectivity	−0.18*	−0.29**	0.03	−0.18*	–	0.37***	0.59***	0.64***
(6) DS14: Social inhibition	−0.10	−0.19*	−0.05	−0.14	0.47***	–	0.13	0.23**
(7) HADS: Anxiety symptoms	−0.45***	−0.56***	−0.20**	−0.53***	0.52***	0.20*	–	0.76***
(8) HADS: Depressive symptoms	−0.51***	−0.38***	−0.22*	−0.50***	0.46***	0.34*	0.67***	–

DS14 = 14-item Type D scale; FPAS = Florida Patient Acceptance Survey; HADS = Hospital Anxiety and Depression Scale.
Above the diagonal = Rotterdam (10 days postimplantation; dark grey); below the diagonal = Enschede (12 months postimplantation; light grey).
All psychological factors are assessed at the same time as the FPAS.
*$P \leq 0.05$; **$P \leq 0.01$; ***$P \leq 0.001$.

between the FPAS and HADS depression ranged from 4% to 34%.

In the Enschede cohort (12 months postimplantation), the FPAS Positive appraisal subscale also did not significantly overlap with the DS14 Negative affectivity subscale. For the other FPAS (sub)scales, the overlap with Negative affectivity ranged from 3% to 8%. None of the FPAS (sub)scales correlated with the Social inhibition subscale of the DS14, except for Device-related distress (4%). The overlap between the FPAS (sub)scales and HADS anxiety and depression ranged from 5% to 31% and from 4% to 26%, respectively.

Despite some overlap between the FPAS and the other psychological measures, in particular with anxiety and depression, these findings suggest that the FPAS measures a construct that is conceptually different from that of personality factors and mood states.

Correlates of Poor Device Acceptance

Overall, both patient cohorts reported a good acceptance of the device, with the mean FPAS total score (12 items) being high at 10 days and 12 months postimplantation (71.8 ± 14.9 and 73.8 ± 16.0, respectively). Correlates of poor device acceptance, that is, the lowest tertile on the FPAS total scale (score ≤64.5), are shown in Table IV. For the Rotterdam cohort assessed at 10 days postimplantation, Type D personality and high depression were independently associated with poorer acceptance of the ICD (OR: 5.04; 95% CI: 1.50–16.92; P = 0.01 and OR: 4.40; 95% CI: 1.04–18.65; P = 0.05, respectively). Of note, as only two patients (1.5%) had received an ICD shock during the 10 days follow-up, ICD shocks were not included as a covariate in the analysis for this cohort.

In the Enschede cohort assessed at 12 months postimplantation, high anxiety (OR: 9.75; 95% CI: 2.38–39.87; P = 0.002) and depression (OR: 2.96; 95% CI: 0.98–8.93; P = 0.05), but not Type D personality (OR: 0.71; 95% CI: 0.22–2.33; P = 0.58), were significant associates of poor device acceptance. None of the demographic or clinical factors were associated with device acceptance.

Discussion

The current study examined the psychometric properties and correlates of the FPAS, a disease-specific questionnaire to assess patient device acceptance, in two cohorts of Dutch ICD patients assessed at 10 days and 12 months postimplantation, respectively. Results indicated that eliminating three items from the FPAS, leaving 12 items contributing to three factors (i.e., Return to function, Device-related distress, and Positive appraisal) is a psychometrically sound alternative to the original 15-item, four-factor version of the FPAS, with validity and internal consistency preserved. Also, our results confirmed that the FPAS measures a construct that is conceptually different from that of mood states and personality, despite some overlap in particular with measures of anxiety and depression. Correlates of device acceptance included anxiety, depression, and

Table IV.

Correlates of Poor Device Acceptance, Stratified by Center[†,‡]

	Rotterdam (10 Days)			Enschede (12 Months)		
	OR	[95% CI]	P	OR	[95% CI]	P
Psychological factors[§]						
Type D personality	5.04	1.50–16.92	0.01**	0.71	0.22–2.33	0.58
Anxiety	2.46	0.49–12.45	0.28	9.75	2.38–39.87	0.002**
Depression	4.40	1.04–18.65	0.05*	2.96	0.98–8.93	0.05*
Demographic factors						
Age	1.03	0.98–1.09	0.22	1.00	0.98–1.05	0.93
Female gender	1.68	0.45–6.22	0.44	0.78	0.19–3.15	0.73
Smoking	0.59	0.12–2.87	0.51	0.96	0.31–2.99	0.94
Clinical factors						
Ischemic etiology	0.77	0.23–2.54	0.67	0.97	0.35–2.85	0.99
NYHA class III/IV	2.36	0.84–6.68	0.10	0.64	0.20–2.06	0.45
LVEF <35%	1.35	0.32–5.71	0.69	1.33	0.41–4.32	0.64
Secondary prevention	0.32	0.08–1.32	0.11	1.48	0.53–4.19	0.46
ICD shock	–	–	–	0.61	0.17–2.26	0.46
Diabetes	0.77	0.16–3.83	0.75	1.48	0.47–4.64	0.50

[†]Multivariable logistic regression analyses.
[‡]All factors, except age, were entered as dichotomous variables.
[§]All psychological factors are assessed at the same time as the FPAS.
NYHA = New York Heart Association functional class; ICD = implantable cardioverter defibrillator; LVEF = left ventricular ejection fraction.
*$P \leq 0.05$; **$P \leq 0.01$; ***$P \leq 0.001$.

Type D personality. Demographic and clinical factors, including ICD shocks, indication, and symptomatic heart failure, were not associated with device acceptance.

The current study confirms that the FPAS is a valid and internally consistent measure of device acceptance, as previously shown in North American and Danish cohorts,[7,11] indicating that the FPAS may be used to assess device acceptance beyond the North American context. Also, the factor structure and internal consistency of the FPAS were confirmed in both of our patient cohorts, assessed at 10 days and 12 months postimplantation, indicating that it is robust over time. However, the results are on par with those of Pedersen and colleagues,[11] who also found that FPAS item 12 (i.e., "I am careful when hugging and kissing my loved ones") was problematic in the Danish context, as it loaded poorly on the expected factor and had a much higher loading on the Body image concerns factor. This suggests that this item is culturally sensitive and if kept in the FPAS, it needs to be rephrased. Also, in both the previous Danish study and the current Dutch study, the Body image concerns factor explained just a small part of the variance in device acceptance (i.e., 6% and 7%, respectively), which might be due to this subscale only containing two items that may be not well formulated. Alternatively, these findings may be explained by the fact that in the current and in the Danish study, the percentage of women was lower than in the North American study (17% vs 37%) and women may have more concerns about their body image than men.[25] However, a recent study has shown no gender differences in ICD acceptance, including body image concerns.[26]

Anxiety, depression, and Type D personality, and not demographic and clinical factors, were associated with poor device acceptance in adjusted analyses. These findings are in line with previous studies, suggesting that the psychological profile of the patient is an equally and sometimes more important determinant of device acceptance and other patient-reported outcomes than disease severity and shocks.[2,6,9,11,14,27] The current results did not confirm those of two Danish studies showing that the presence of symptomatic heart failure was a determinant of poor device acceptance.[2,11] This could be explained by the fact that in the current study, physician-rated indicators of heart failure severity (i.e., NYHA

functional class and LVEF) were used, while in the Danish studies, symptomatic heart failure was based on a score on the Minnesota Living with Heart Failure questionnaire, a patient-reported health status measure. Hence, an expansion of the focus beyond traditional indicators of disease severity and shocks to also include psychological and patient-reported determinants is essential to identify patients at high risk for adjustment difficulties after device implantation.[28]

Most studies, including our study, however, indicate that ICD patients generally view their device positively and experience low levels of device-related distress, even after being subjected to shock(s) or a device advisory notice.[3,8–10] The FPAS may be especially useful for examining the normative processes of adjustment to ICD therapy as it does not focus on maladjustment or psychopathology.[14] Hence, the FPAS is applicable to all patients. In addition, the FPAS has been shown to detect changes in psychological well-being following psychosocial intervention,[29] suggesting that it is a sufficiently sensitive measure to tap changes in outcome, if present, following an intervention.

Previously, poor device acceptance has been associated with more emotional distress and impaired quality of life.[2,6] Hence, the FPAS could be used to identify patients at risk for poor patient-reported outcomes who need adjunctive treatment. Psychosocial intervention, in particular cognitive-behavioral therapy and patient education, has been shown to have beneficial effects on device acceptance, quality of life, and psychological distress levels in ICD patients.[29,30]

The limitations of the present study must be acknowledged. First, the study design was cross-sectional, and therefore, it is not possible to infer cause and effect. A future prospective study is warranted to determine whether psychological distress is a precursor of poor ICD acceptance or vice versa. Second, psychological variables were only assessed by means of self-report rather than interviews. However, all questionnaires were standardized and validated. Third, the FPAS was dichotomized using the lowest tertile in order to be consistent with previous studies in North American and Danish cohorts that used the same cut-off.[2,6,11] However, more research is needed to determine the clinical relevance of this cut-off point.

Strengths of the current study were its relatively large sample size, the comparison of two independent ICD patient cohorts assessed at a different times postimplantation, and the inclusion of physician-rated information on disease severity, that is, LVEF and NYHA functional class, in adjusted analyses.

In conclusion, the present study shows that the FPAS is a valid and internally consistent measure of patient device acceptance. Based on previous Danish findings and findings of the current study, we would suggest that the FPAS be shortened to a 12-item version assessing three factors. Abbreviation of the FPAS from the original 18 items to 12 items also makes it more suitable to use in research and clinical practice due to its brevity. However, until the findings of these two studies are confirmed in ICD cohorts in other countries, both the 12-item and the 18-item version of the FPAS could be used. The present and previous findings indicate that a small subgroup of patients experience difficulties with adjustment following ICD implantation, and that this likely is attributable not only to the severity of their disease and shocks but also to their psychological profile. The FPAS is a useful tool in research and clinical practice to examine the process of device adjustment and to identify patients at high risk for psychological difficulties after ICD implantation. Future intervention studies with a prospective design are warranted to examine how device acceptance can be augmented and the implications for well-being and health outcomes of ICD patients.

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Appendix:

Means and Standard Deviations for the Alternative Dutch FPAS (12 items, three factors, N = 272)*

FPAS Items	Original Item No.	Raw Score†	Linearly Converted Score‡
Device-related distress		16.98(3.05)	81.11 (19.09)
(1) Thinking about the device makes me depressed.	1	1.99(1.08)	
(2) When I think about the device, I avoid doing things I enjoy.	2	1.82(0.97)	
(3) I avoid my usual activities because I feel disfigured by the device.	3	1.45(0.76)	
(4) It is hard for me to function without thinking about my device.	4	1.76(0.95)	
Positive appraisal		16.12(3.16)	75.74 (19.78)
(5) My device was my best treatment option.	5	4.06(1.01)	
(6) I am safer from harm because of my device.	7	3.98(1.03)	
(7) The positive benefits of this device outweigh the negatives.	8	3.97(1.09)	
(8) I would receive this device again.	10	4.11(0.90)	
Return to function		13.86(3.78)	61.65 (23.62)
(9) I am confident about my ability to return to work if I want to.	6	3.36(1.33)	
(10) I have returned to a full life.	13	3.59(1.14)	
(11) I am not able to do things for my family the way I used to.	17	2.71(1.28)	
(12) I am concerned about resuming my daily physical activities.	18	2.38(1.21)	
Total		49.96(7.43)	72.83 (15.49)

Results are presented as mean (SD).

†Raw scores: Device-related distress = item 1^r + item 2^r + item 3^r + item 4^r; Positive appraisal = item 5 + item 6 + item 7 + item 8; Return to function = item 9 + item 10 + item 11^r + item 12^r; total score = item 1^r + item 2^r + item 3^r + item 4^r + item 5 + item 6 + item 7 + item 8 + item 9 + item 10 + item 11^r + item 12^r, where ^{r} = use reversed item score.

‡Linearly converted scores: subscale scores = ((raw subscale score – 4)/16) × 100; total score = ((raw total score –12)/48) × 100.